

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

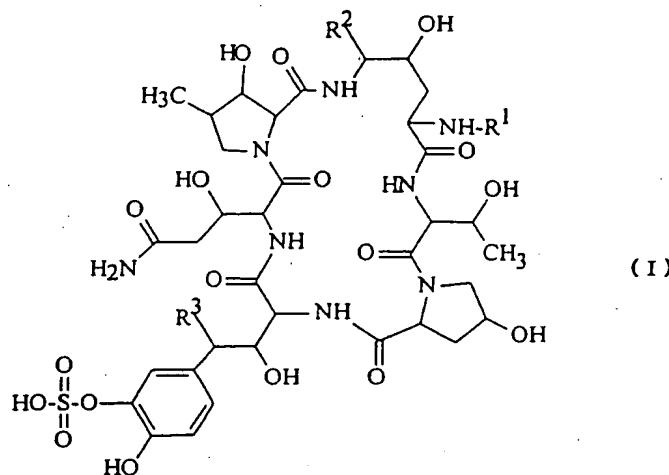
- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

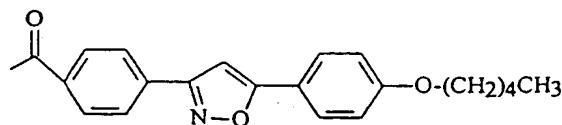
CLAIMS

1. A stabilized pharmaceutical composition in lyophilized form which comprises:
- 5 a cyclic polypeptide compound of the general formula (I) :



- wherein R<sup>1</sup> is a hydrogen atom or an acyl group and R<sup>2</sup> and R<sup>3</sup> are, the same or different, a hydrogen atom or a hydroxyl group,
- 10 or its pharmaceutically acceptable salt as an active ingredient, and one or more suitable stabilizer(s) selected from the group consisting of a polysaccharide, a disaccharide and sodium chloride.

2. A composition according to claim 1 in which R<sup>1</sup> is represented by
- 15 the formula:



and R<sup>2</sup> and R<sup>3</sup> are hydroxy groups.

3. A composition according to claim 1 in which the stabilizer is a disaccharide.
  4. A composition according to claim 3 in which the disaccharide is lactose, maltose or sucrose.
  5. A composition according to claim 4 in which the disaccharide is lactose.
- 10 6. A composition according to claim 1 which contains 0.4 to 50 parts by weight of the stabilizer with respect to one part by weight of the cyclic polypeptide compound or its pharmaceutically acceptable salt.
- 15 7. A composition according to claim 1 which contains 0.1 to 400 mg of the cyclic polypeptide compound or its pharmaceutically acceptable salt in a single unit dose.
- 20 8. A composition according to claim 1 prepared by the steps of: dissolving the cyclic polypeptide compound (I) or its pharmaceutically acceptable salt, the stabilizer and optionally a pH adjustor in a purified water and lyophilizing the solution.
- 25 9. A composition of claim 1 which, when dissolved in purified water, gives a solution of pH 4.0 to 7.5.
10. A composition of claim 1 containing 3.4 % by weight or less of water.
- 30 11. A use of the cyclic polypeptide compound (I) or its pharmaceutically acceptable salt for preparing the stabilized pharmaceutical composition in lyophilized form containing the stabilizer.

12. An injection preparation prepared by dissolving the composition of claim 1 in isotonic sodium chloride solution.
13. A use of a polysaccharide, a disaccharide and sodium chloride as  
5 a stabilizer for a stabilized pharmaceutical composition in lyophilized form.
14. A use according to claim 13, wherein the stabilized pharmaceutical composition in lyophilized form is a composition as set  
10 forth in claim 1.
15. A commercial package comprising the pharmaceutical composition of any one of claim 1 to claim 10 and a written matter associated therewith, wherein the written matter states that the  
15 pharmaceutical composition can or should be used for preventing or treating infections disease.